DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-849/S-004

Baxter Healthcare Corporation
Route 120 and Wilson Road
Round Lake, IL 60073
Attention: Marcia Marconi
Vice President, Regulatory Affairs

14 NOV 2001

Dear Ms. Marconi:

Please refer to your supplemental new drug application dated December 10, 1999, received December 14, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for 20% ProSol™ - sulfite-free (amino acid) Injection in Viaflex® Plastic Container.

We acknowledge receipt of your submission dated October 3, 2001. Your submission of October 3, 2001, constituted a complete response to our June 18, 2001, action letter.

This supplemental new drug application responds to the Final Rule published in the CFR on December 13, 1994, titled *Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Revision of Pediatric Use" Subsection in the Labeling.*

We have completed the review of this supplemental application, as amended, and it is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Victoria Kao, Project Manager, at (301) 827-7416.

Sincerely,

Cynthia G. McCormick, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research